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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,841	09/23/2003	Lawrence Blatt	MBHB02-249-E(400.042US)	2643

20306 7590 04/05/2007
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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/669,841

Applicant(s)

BLATT ET AL.

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,11-18 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/5/2004, 8/29/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of "2'-deoxy-2'-fluoro nucleotides" in the reply filed on 12/5/2006 is acknowledged. Applicant traverses the species election requirement regarding the linkers of claims 22-24. However, the restriction requirement with respect to claims 22-24 is moot because applicant has cancelled claims 22-24.

Upon further consideration, the species election requirement between 2'-O-methyl, 2'-fluoro, 2'-deoxy and 2'-allyl modifications is withdrawn.

Claims 1, 2, 9, 11-18 and 25-27 are pending in the instant application.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for each of

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the instant claim limitations. Applicant points to application 60/358,580 for support of the instant claim amendments, however upon a review of application '580, support for each of the instant limitations is not apparent. For example, application '580 does not teach "siNA" molecules and does not teach such molecules wherein "about 100% of nucleotides in one or both strands" are chemically modified. Furthermore, application '580 does not teach siNA molecules comprising a "distinct" sense strand or siNA molecules wherein the sense strand is complementary to the antisense strand and further comprises a portion of the HBV sequence of about 18 to about 27 nucleotides in length.

Furthermore, applicant points to application '580 for support based on incorporation by reference of the '580 application in the instant specification. However, the claims are essential subject matter. Essential subject matter may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, whereas application '580 is a provisional application. See MPEP 608.01(p) and 37 CFR 1.57.

Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 12/5/2006 in each of the claimed priority documents. In view of the new matter rejection below, the instant claims are accorded an effective filing date of the instant application, which is 9/23/2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9, 11-18 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "the sense strand is complementary to the antisense strand and further comprises a portion of said HBV nucleotide sequence of about 18 to about 27 nucleotides". The instant specification does not contemplate siNA molecules wherein the sense strand is complementary to the antisense strand and further comprises about 18 to about 27 more nucleotides that are a portion of the HBV nucleotide sequence. Furthermore, since part a) of claim 1 requires for each strand of the siNA molecule to be about 18 to about 27 nucleotides in length, it is unclear how the sense strand can further comprise about 18 to about 27 nucleotides in excess of the portion that is complementary to the antisense strand.

Claims 2, 9, 11-18 and 25-27 are rejected because they depend from instant claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 9, 11-18 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 1 recites "comprising a distinct sense strand and an antisense strand", which was newly introduced in the claim amendments filed on 12/5/2006. Claim 1 recites "the sense strand is complementary to the antisense strand and further comprises a portion of said HBV nucleotide sequence of about 18 to about 27 nucleotides", which was newly introduced in the claim amendments filed on 12/5/2006. However, the instant specification does not teach a limitation wherein the siNA molecule comprises a "distinct" sense strand and does not contemplate siNA molecules wherein the sense strand is complementary to the antisense strand and further comprises about 18 to about 27 more nucleotides that are a portion of the HBV nucleotide sequence.

These newly introduced limitations to the claims constitute new matter. Furthermore, there is no support for these claim limitations in the claimed priority documents. Therefore, the effective filing date of the instant claims is considered, for purposes of prior art, to be 9/23/2003, which is the filing date of the instant application. Claims 2, 9, 11-18 and 25-27 are rejected because they depend from claim 1.

Claim 1 recites, "double stranded short interfering nucleic acid (siNA) molecule comprising a distinct sense strand and an antisense strand". However, the instant

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specification does not contemplate "double stranded short interfering nucleic acid (siNA)" molecules and does not teach such molecules having a distinct sense and antisense strand and does not teach siNA molecules that are "about 18 to about 27 nucleotides in length". The instant specification does not teach siNA molecules having an antisense strand comprising nucleotide sequence of about 18 to about 27 nucleotides that are complementary to a conserved region of HBV RNA or a sense strand that is complementary to the antisense strand and further comprises a portion of the HBV nucleotide sequence of about 18 to about 27 nucleotides.

Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where support might exist for each claim limitation added in the amended claims filed on 12/5/2006.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 9, 11-18, 26 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 15, 16, 18-21, 23, and 32-35 of copending Application No. 10/244,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '647 are directed to siNA molecules with the same structural limitations that are targeted to the same target, HBV. The instant claims and the claims of application '647 render each other obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

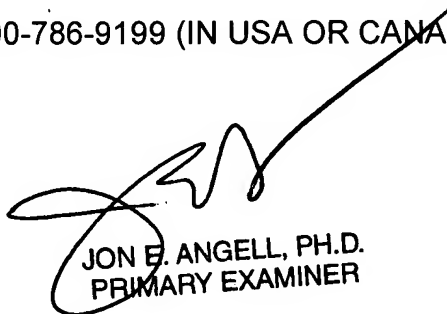
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON E. ANGELL, PH.D.
PRIMARY EXAMINER

AHB

Amy H Bowman
Examiner
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